HHS Public Access

Author manuscript

Int J Tuberc Lung Dis. Author manuscript; available in PMC 2016 December 06.

Published in final edited form as:

Int J Tuberc Lung Dis. 2014 November ; 18(11): 1347–1352. doi:10.5588/ijtld.14.0242.

Longevity loss among cured tuberculosis patients and the potential value of prevention

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SUMMARY

BACKGROUND—Evidence of substantial, quantifiable and preventable burdens of mortality hazard even after anti-tuberculosis treatment and cure would be a compelling, concrete, and useful measure of the value of prevention.

METHODS—We compared years of potential life lost between a cohort of 3 933 cured tuberculosis (TB) patients and 9 166 persons with latent tuberculous infection. We constructed a regression model to predict the expected years of potential life lost in each cohort and for demographic subgroups.

RESULTS—Among decedents, a history of fully treated TB is associated with a predicted average 3.6 more years of potential life loss than a comparable population without active TB. Greater longevity losses were predicted among those identified as White and Hispanic than among Black and Asian counterparts.

CONCLUSION—We found significant differences in predicted longevity of treated TB survivors relative to a similar group without active TB. These excess losses are substantial: a total of 14 158 life-years or the equivalent of more than 188 75-year lifespans. These findings illustrate an important opportunity cost associated with each preventable TB case — an average of 3.6 potential years of life. We conclude that substantial preventable mortality burdens remain despite adequate anti-tuberculosis treatment, a compelling rationale for more widespread and systematic use of prevention.

RESUME

Les preuves d'un risque accru de mortalité substantiel, quantifiable et évitable même après un traitement anti-tuberculeux et une guérison serait un argument fort, concret et utile en faveur de la prévention.

Nous avons comparé les années de vie perdues potentielles entre une cohorte de 3933 patients tuberculeux guéris et une autre de 9166 personnes ayant une infection tuberculeuse latente. Nous

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Conflict of interest: none declared.

avons construit un modèle de régression afin de prédire les années potentielles de vie perdues dans chaque cohorte et dans les différents sous-groupes démographiques.

Parmi les patients décédés, une histoire de tuberculose (TB) complètement traitée est associée à une moyenne prévue de 3,6 années potentielles de vie perdues par rapport à une population similaire sans TB active. De plus grandes pertes de longévité ont été prédites chez les personnes de race blanche et hispanique par rapport à leurs homologues noirs ou asiatiques.

Nous avons trouvé des différences significatives dans les prédictions de longévité de patients ayant survécu à une TB traitée par comparaison à un groupe similaire sans TB active. Ces pertes en excès sont substantielles : un total de 14 158 années de vie ou l' équivalent de plus de 188 durées de vie de 75 ans. Ces constatations illustrent les coûts d'opportunité élevés associés à chaque cas de TB évitable — une moyenne de 3,6 années de vie potentielles. Nous concluons qu'un fardeau substantiel de mortalité évitable persiste en dépit du traitement approprié de la TB, ce qui constitue un argument irréfutable en faveur d'une utilisation plus vaste et systématique de la prévention.

RESUMEN

Las pruebas de la existencia de cargas considerables, cuantificables y prevenibles de un riesgo de mortalidad, incluso después del tratamiento, y la curación de la tuberculosis (TB) podrían representar medidas convincentes, concretas y útiles de la importancia de la prevención.

Se compararon los años de vida potencial perdidos de una cohorte de 3933 pacientes curados de TB y 9166 personas con infección tuberculosa latente. Se construyó un modelo de regresión destinado a predecir los años de vida potencial perdidos previstos en cada cohorte y en los subgrupos demográficos.

En los difuntos, un antecedente de TB con tratamiento completo se asoció con un promedio de 3,6 años de vida potencial perdidos, con respecto a una población comparable sin TB activa. Se pronosticaron mayores pérdidas de longevidad en las personas de etnia blanca o hispánica en comparación con sus homólogos de etnia negra o asiática.

Se observaron diferencias significativas en la longevidad prevista de los sobrevivientes del tratamiento antituberculoso en comparación con un grupo análogo de personas sin TB activa. Estos excesos de pérdidas son considerables, un total de 14 158 años de vida o el equivalente de más de 188 vidas de 75 años. Los resultados del estudio ponen de manifiesto un importante coste de oportunidad asociado con cada caso de TB prevenible, en promedio de 3,6 años de vida potencial. Se concluye que pese al tratamiento adecuado de la TB, persisten importantes cargas prevenibles de mortalidad, que constituyen un argumento convincente en favor de la aplicación de una prevención más generalizada y sistemática.

Keywords

mortality; premature death; regression

Tuberculosis (TB) is often considered a curable disease without lasting post-cure sequelae,[1] but an assumption that cure reliably restores patients to their baseline health may be incorrect. While cavitary lesions typically disappear on computerized tomography (CT)

scans following cure,[2,3] there is evidence to suggest that poor health may linger long after treatment is completed and the patient is discharged from care.[4–8] Such health deficits may be associated with a shortened lifespan.

TB is preventable. Well-established epidemiologic and clinical protocols exist to diagnose latent tuberculous infection (LTBI), evaluate risk for activation to TB disease, and reduce that risk through a course of antibiotics where indicated.[9,10] As the limitations of cure as a fully adequate harm reduction strategy become better understood, TB control and elimination paradigms have begun to evolve. Clinicians and public health authorities are rethinking treatment and other decisions predicated on the assumption that cure and prevention produce equivalent health outcomes, as well as the notion that active TB is a discrete episode in a patient's lifetime that ends with the completion of standard treatment.[11] For more than a decade, national medical organizations and the Centers for Disease Control and Prevention (CDC, Atlanta, GA, USA) have recommended targeted testing and treatment of persons at high risk of LTBI as a priority for controlling TB in the United States.[9,12] However, these recommendations have not been widely implemented,[13,14] partly because of poor acceptance by health professionals,[15] but also due to limited public health resources.[16]

Effective and efficient advocacy or allocation of system resources requires an evidence-based comparison of outcomes to weigh the potential costs and benefits of various strategic choices or investments. Work has been done to identify TB-related morbidity and mortality taking place in the period between infection and death or cure,[17] and the pulmonary impairment as well as relative mortality risks faced by former TB patients have been described.[8] Nevertheless, the residual burdens of morbidity and mortality risks that remain after cure have not been quantified, and the marginal health losses associated with the failure to interdict a potentially preventable TB case, and the potential gains available from prevention, remain unknown. We sought to fill this knowledge gap by estimating the absolute burden of TB-associated mortality within a defined cohort of persons known to have completed anti-tuberculosis treatment. Our estimates will increase the understanding of the unmeasured health consequences of active TB and provide insight into the long-term benefits of TB prevention.

METHODS

The Tuberculosis Epidemiologic Studies Consortium (TBESC) is a partnership between the CDC's Division of Tuberculosis Elimination and academic and public health collaborators at 20 US sites.[18] We used records from three of the TBESC sites, Texas, Massachusetts, and Washington's Seattle/King County, to create a database for two groups: persons who had completed treatment for TB disease at least 6 years previously and a comparison population of persons with diagnosed LTBI.[19,20]

Criteria for inclusion in the database included 1) age ≥18 years at treatment initiation (for TB) or diagnosis (for LTBI); 2) sufficiently comparable demographic, clinical, and other data to allow adjusted analyses; and 3) sufficient identifiers to determine vital status in the National Death Index (NDI). In addition, TB survivors had to have 1) TB diagnosed, reported, and treatment completed between 1 January 1993 and 31 December 2002; 2)

treatment completed within 3 years of initiation; and 3) alive at treatment completion. Additional criteria for inclusion in the comparison group were 1) an LTBI diagnosis recorded during the same 10-year period as cases, and 2) no documented history of previous TB disease. We patterned our choice of LTBI diagnosis as a basis for comparison with similar methods used to evaluate pulmonary impairment after TB.[8] Whether a potential comparison subject has received LTBI treatment is not relevant to our intended adjustment for generalized non-TB risk factors such as lifestyle and socio-economic status, and was thus not considered in the eligibility criteria.

We used the CDC NDI to determine the vital status of persons in the two groups as of 31 December 2008, allowing 6–16 years of retrospective observation for each subject. The NDI uses a probability algorithm to compare submitted data on full name, sex, birth date, and (when available) Social Security number with its death records 1) to classify persons with regard to vital status, and 2) to assess the strength and precision of the identifying information. Subjects classified by NDI with a probability score above the recommended cut-off threshold were defined as deceased, allowing a positive predictive value for mortality of >89%.[21–23] The final results were de-identified for analysis.

Protocols for data collection and analysis were approved by the Texas Department of State Health (DHSH) Institutional Review Board (IRB), The University of North Texas Health Science Center Office for the Protection of Human Subjects (Fort Worth, TX, USA), and the CDC's central IRB, as well as the respective IRBs of each participating site.

We calculated years of potential life lost (YPLL) for both groups. The YPLL represents the potential loss to death for each individual, and where the average difference of YPLL between the two cohorts is unequal, it indicates some disparity. YPLL were calculated using the life expectancy method.[24] Where a subject had died, and YPLL were identified, we quantified that loss using the United States Life Tables, 2006.[25] The YPLL therefore represents the individual's difference between the observed age at death and the expected sex- and age-adjusted life expectancy, and this value was included as an additional data point for regression analysis. Because death was a relatively uncommon event during the observation period, a zero-inflated Poisson (ZIP) regression model was fitted to predict the expected YPLL in each cohort.[26,27] The coefficients from the Poisson portion of the regression model (the expected YPLL) were used to predict the YPLL and absolute loss attributable to TB for population subgroups. The model controlled for known human immunodeficiency virus (HIV) status, TB history, age at treatment completion (for TB survivors) or entry into observation (for comparison subjects), time under observation, and demographic variables. If the HIV status was missing, it was assumed to be negative. The average predicted YPLLs were obtained for various subgroups. To test the effect of HIV and past TB disease on premature mortality, a separate ZIP regression analysis was modeled that excluded the 748 known HIV-positive cases and controls, and predicted YPLLs were compared between the HIV-inclusive group and the HIV-excluded group.

Summary YPLLs were calculated in a separate analysis to compare the loss of years in both cohorts and to help adjust for the relatively younger control group. YPLLs for 10-year age categories ranging from 18 to 85 years were calculated by subtracting the midpoint of each

age group from 85. The number of deaths in each age stratum was multiplied by the YPLL for that group and summed for each cohort.[28] All analyses were performed using Stata Statistical Software Release 12 (StataCorp, College Station, TX, USA, 2011).

RESULTS

The final database included a cohort of 3933 cured TB patients and a comparable population of 9166 persons with LTBI. The demographic characteristics of case and control subject cohorts are shown in Table 1. Significant differences were present in the distribution of sex, race/ethnicity, age at entry into observation, geographic location, HIV status, foreign birth, and survival through the end of the observation period.

The LTBI comparison cohort was younger at enrollment (87.5% aged <50 years compared to 61.9% of the TB survivors, $P < 0.001$) and twice as often enrolled under the age of 30 years. TB survivors were about nine times more frequently enrolled at age ≥70 years than LTBI comparison subjects. By the end of the 11-year observation period, 867 (22%) of the TB group and 364 (4%) of the LTBI group had died.

Expected life loss potentially attributable to TB

Sex-, race-, age-, HIV status- and nativity-controlled analysis predicted higher rates of longevity loss among study subjects with a history of fully treated TB relative to those with LTBI but no history of disease (incidence rate ratio 1.24, $P < 0.001$). Table 2 compares the predicted average YPLL for those who died during the observation period in the cured TB group and the LTBI control group. Cohort-wide, an adjusted average of 4.89 years are lost to those dying after completion of anti-tuberculosis treatment compared to a loss of 1.28 years from those dying after enrollment into the LTBI comparison group ($P < 0.001$). Subjects with both HIV infection and a history of TB were predicted to lose on average 16.3 potential life years ($P < 0.001$), and a sensitivity analysis exploring how robustly the full model controlled for the effects of HIV predicted less than half a year YPLL difference from the full model (data not shown). Among decedents, a history of fully treated TB is associated with an average 3.6 years of potential life loss relative to a comparable population with no history of active TB disease. Greater life loss is predicted for White and Hispanic TB survivors than for their Black and Asian counterparts, while immigrants were less likely to lose years of potential life compared to survivors born in the United States. Overall, a total of 14 035 YPLLs can be expected from the TB cohort (data not shown).

DISCUSSION AND IMPLICATIONS FOR POLICY AND PRACTICE

We found a greater-than-expected mortality burden in the years following anti-tuberculosis treatment completion relative to a similar population with no history of TB disease. On average, decedents with a history of fully treated TB lost an adjusted average of 4.89 potential years of life relative to their sex-adjusted life expectancy. More significantly, most of this loss, 3.6 years, is associated with a history of active but fully treated TB. This TB-attributable burden suggests another potential benefit associated with its prevention. In our study cohort of fewer than 4000 case subjects, these excess losses are substantial — a total of 14 158 life-years, or the equivalent of more than 188 75-year lifespans. Put another way,

these findings suggest that progress toward domestic elimination goals with a focus upon prevention comes with a tangible and important benefit beyond those commonly considered —each incident case prevented may preserve an average of 3.6 potential years of life.

Our findings are consistent with those of others who found increased mortality in TB survivors compared to the national population.[29,30] We used two different analytical models as well as alternative methods to evaluate the substantial difference in unadjusted death rate between cases and controls (22% and 4%, respectively). Our estimates remained robust, with consistent findings of a strong association between loss of potential life-years and TB survivorship, a potential loss similar to the more well-known attributable losses from tobacco use and obesity.[31,32]

This study has potential limitations, generally related to potential ascertainment and other biases that may arise from the use of administrative records as a data source. The original data set was collected retrospectively, and the maximum available duration of observation for any subject was ≤16 years. It is possible that premature mortality among TB survivors may continue beyond that period, which may lead to an underestimated mortality burden. It is feasible that the subjects captured in our data may not fully represent the populations we compared. In addition, both our analysis and the initial vital status determination were limited by missing data for risk and other variables related to individual study subjects. Missing data were not evenly distributed, and due to the nature of TB reporting and record keeping, we noted that data were more often missing from the control group. There are further limitations to the use of LTBI as a control group. Ascertainment bias could be present due to the circumstances leading to the report of past infection, such as incarceration or immigration. When LTBI status is determined, other risk factors, such as HIV status, may not be as diligently recorded compared to TB cases. It is likely true that TB is a marker for generally poor health and that some premature mortality identified in this population is due to predisposing factors for active TB, such as untreated comorbidities, drug or alcohol abuse or poor nutrition rather than sequelae of the disease itself. However, the chronic morbidities and the pulmonary and other impairments these impart are well understood, as are the population risks shared by those with LTBI and active TB.[2–8] Given this, it seems likely that our premise and comparison methodologies are sufficient to plausibly explain a measurable association between a history of active TB and disproportionate premature death.

We found greater odds of survival among foreign-born subjects, and other studies have shown reduced mortality from active TB in immigrants.[33,34] The differences seen in our study may support the ‘healthy immigrant’ hypothesis that relocation to another country is most likely to be practiced by healthier people, but our study did not capture deaths in study subjects who left the United States during or after the observation period, and we were unable to assess the time spent in the United States. Recent studies have noted that recent immigrants report a higher level of health than native-born persons, but the difference diminishes with increased tenure in the United States.[35] Finally, although our data represent a diverse population from three distinct areas of the United States, findings drawn from analysis of only three geographic locations may not be fully generalizable to the US or other populations. We conducted analyses to identify the impacts of potential sampling bias and

data limitations as well as sensitivity to model selection, but found no evidence to fundamentally compromise our conclusions.

The difficulty in the elimination of remaining cases of TB in industrialised nations is that new cases and pockets of LTBI are clustered in hard-to-reach populations such as immigrants, the incarcerated, and the homeless. The political will to pursue an increasingly difficult and expensive goal of TB elimination is not certain, and evidence to shore up that political aim is vital. Our study suggests that even fully treated TB may not avert a substantial mortality burden, a compelling rationale for public investment and support for TB prevention.

Reducing the burden of TB in the United States and defining a path to elimination will require significant changes, not only to policy and practice, but also to the concept that treating LTBI is, from a societal standpoint, as important as treating active disease. Our understanding of how and when TB damages health continues to be challenged, and there is mounting evidence that the burden of TB does not end with the completion of adequate treatment. The association between potential life loss and past TB adds to that evidence and demonstrates that the burden is larger than realized. Further research may elucidate underlying risk factors for reduced longevity, and we recommend that long-term sequelae and death should be studied when assessing effectiveness of prevention.

Notwithstanding this somber news, we are also able to offer an additional conclusion that is much more optimistic: the means to achieving TB elimination through diligent prevention efforts are already available, are well accepted, and, given evidence such as that presented in this work, may be more valuable and efficient than currently understood.

Acknowledgments

The authors gratefully acknowledge the support of the US Centers for Disease Control and Prevention's Division of Tuberculosis Elimination and its Tuberculosis Epidemiologic Studies Consortium (Atlanta, GA, USA), as well as the dedicated and tireless staff of Tarrant County Public Health (Fort Worth, TX, USA), both of which provided structure and guidance to make this work possible. The authors also acknowledge the valuable intellectual and other contributions made by S Weis with the University of North Texas Health Science Center.

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Table 1

Characteristics of TB survivors (case subjects) and LTBI comparison cohorts

Characteristic	Case subjects *n* (%)	Comparison subjects *n* (%)	*P* value*
Sex†			
Male	2453 (62.2)	4960 (56.0)	<0.01
Female	1480 (37.6)	3890 (44.0)	<0.01
Race			
White	940 (23.9)	2890 (31.5)	<0.01
Black	981 (24.9)	1914 (20.9)	<0.01
Asian	1049 (26.7)	1757 (19.2)	<0.01
Hispanic	920 (23.4)	2519 (27.5)	<0.01
Other or unknown	43 (1.1)	86 (0.9)	<0.01
Age at cohort entry, years‡			
18–30	788 (20.0)	3809 (41.6)	<0.01
30–50	1646 (41.9)	4210 (45.9)	<0.01
50–70	993 (25.2)	1019 (11.1)	<0.01
>70	506 (12.9)	128 (1.4)	<0.01
Geographic location			
Massachusetts	1293 (32.9)	3320 (36.2)	<0.01
Seattle/King County	984 (25.0)	2515 (27.4)	
Texas	1656 (42.1)	3331 (36.3)	
Known HIV-positive	350 (8.9)	398 (4.3)	<0.01
Foreign-born†	2279 (57.9)	4964 (54.1)	<0.01

*χ^2 test was used to compare binary or categorical variables.

†Sex and foreign birth categories do not sum to *n* due to missing data.

‡Student's *t*-test was used to compare age at diagnosis.

TB = tuberculosis; LTBI = latent tuberculous infection; HIV = human immunodeficiency virus.

Table 2

Predicted YPLL by individual characteristics and TB history

	TB Predicted YPLL (95%CI)	LTBI Predicted YPLL (95%CI)	Absolute loss of years attributable to TB
TB vs. LTBI	4.89 (4.27–5.51)	1.28 (1.10–1.47)	3.61
Sex			
Male	4.74 (4.13–5.34)	1.24 (1.06–1.42)	3.50
Female	5.11 (4.46–5.77)	1.34 (1.14–1.54)	3.77
Race			
White	5.77 (4.77–6.78)	1.53 (1.25–1.82)	4.24
Black	4.02 (3.26–4.78)	1.05 (0.83–1.27)	2.97
Asian	4.27 (3.34–5.20)	1.11 (0.84–1.38)	3.16
Hispanic	5.40 (4.44–6.35)	1.42 (1.14–1.69)	3.98
HIV-positive	16.33 (13.25–19.43)	4.64 (3.58–5.70)	11.69
Foreign-born	3.15 (2.63–3.67)	0.81 (0.67–0.95)	2.34

YPLL = years of potential life lost; TB = tuberculosis; CI = confidence interval; LTBI = latent tuberculous infection; HIV = human immunodeficiency virus.